

## **REMARKS/ARGUMENTS**

### **Amendment to the specification**

As per the Examiner's suggestion, a newly presented abstract has been produced deriving from the abstract found on the PCT application page.

### **Amendment to the claims**

Rejection to claim 11 has been rendered moot by its cancellation.

Similarly, rejections to claims 10 and 11 have been rendered moot due to their cancellation.

### **Claims Rejection under 35 U.S.C. §112 second paragraph**

Claims 1 to 12 have been rejected under 35 U.S.C. §112 second paragraph as indefinite for failing to point out and distinctly claim the subject matter which the Applicant regards as the invention. The Applicant respectfully requests reconsideration.

Claim 1 is directed at a porous biomechanically biocompatible TiNi material with a matrix of TiNi having a specific structure of struts and a percentage of nickel and titanium and further including composite precipitates interspersed within the matrix and a distribution of pore sizes that afford the material its biocompatibility. The TiNi material further has an atomic oxygen concentration and is devoid of nickel enriched secondary phases. The Applicant respectfully submits that the claim clearly outlines the scope of the product claimed to one of ordinary skill in the art. Reconsideration is respectfully requested.

The rejection of claims 10 and 11 under the same Section has been rendered moot with their cancellation.

Claim 1 has also been amended with the deletion of the parentheses on line 2 for greater clarity.

Claim 12 has been cancelled.

With respect to the objection with regard to the expression in claim 1 “having mechanical properties suitable for surgical implantation” the Applicant submits that the specification starting at paragraphs [0035] to [0040] and including Table 3 clearly outlines the properties that are suitable for such implantation.

Claims Rejection under 35 U.S.C. §112 first paragraph

The claims on file have been rejected as failing to comply with the enablement requirement. Particularly, the objection is that the specification would not permit one skilled in the art to make and/or use the invention, by merely describing the end product, the applicant’s invention does not necessarily satisfy the requirement. Applicant respectfully requests reconsideration.

It is respectfully submitted that the present application describes the invention in sufficient detail and precision to allow one of ordinary skill in the art, a powder metallurgist to understand and arrive at the subject matter of the claims. Various prior art references including “*Shape Memory Alloy Characterization and Optimization*”, authored by Anja Serneels, (Proceedings of the First European Conference on Shape Memory and Superelastic Technologies, September 5-9, 1999 Antwerp Zoo, Belgium) would be known to one of ordinary skill in the art and teach the transformation of titanium/nickel, TiNi, alloys between a martensitic and austenitic condition. The Serneels reference further teaches that small compositional changes result in large shifts in transformation temperature especially on the nickel rich side. At the titanium rich side, because of precipitation of titanium rich precipitates, the matrix composition and therefore the transformation temperature remain the same. Thus for high transformation temperatures a titanium rich alloy will be selected. The formation of nickel rich precipitates gives intrinsic strength to the material and will also result in an increase in the transformation temperatures. It is respectfully submitted that the prior art teaches that nickel rich precipitates are formed by increasing the nickel concentration in the titanium nickel alloy and that titanium rich precipitates are formed by increasing the titanium concentration in the nickel titanium alloy. Therefore, one of ordinary skill in the art, would understand that modifying the mix of composition of the two components from an equiatomic ratio of nickel versus titanium (1:1) to either higher or lower ratios of nickel to titanium by respectively increasing the weight percentages of either nickel

or titanium powder, would produce respectively either more nickel or titanium enriched phases.

With regard to the oxygen concentration, the prior art teaches various intermetallics such as TiNi can be produced by a Self-propagated High temperatures Synthesis (SHS) reaction also known as a combustion synthesis reaction as well as other processes such as sintering. The combustion synthesis technique and its potential are disclosed in various publications including the article by Z. A. Munir *et al.* in *Materials Science Reports*, Vol. 3 (1989), page 279; J. B. Holt *et al.* in *the Annual Review of Material Science*, Vol. 21 (1991), page 305; and J. J. Moore *et al.* in *Progress in Material Science*, Vol. 39 (1995), page 243. Various patents can also serve as background information, including U.S. Patents 4,732,556; 4,948,761; and 4,957,885. The SHS process has various advantages that include: a low energy requirement; a fast reaction rate and short reaction time; a relatively simple process; and the production of porous structures. It is submitted that this type of reaction is also well suited for some degree of routine trial and error experimentation.

The applicant respectfully submits that despite the view of the Examiner, the oxygen levels can be regulated in at least three ways suggested in the disclosure: either by control of the atmosphere of reaction (through air scavenging or purging of reactor), by control of oxygen concentration in the raw material or in by using a combination of both methods. By varying these parameters through routine manipulation one of ordinary skill in the art would arrive at the product claimed.

With regard to the intermetallics having a TiNi composition, it is apparent that the prior art fails to teach or even suggest oxygen concentrations, however armed with background information and through routine trial and error testing, one of ordinary skill in the art could begin with titanium and nickel powders ratios claimed and the goal of oxygen control during the SHS process and could realize both the oxygen concentration and the pore size and shape.

Finally, the prior art also teaches that annealing is commonly used in metallurgic processes and is understood to produce different metallurgical phases in a product. Annealing is also known to have an important influence on mechanical properties of the

product being annealed. U.S. Patent 6,533,905 describes a method of sputtering titanium nickel memory alloys. When a desired film thickness is reached the sputter deposition step is terminated and the thin film expanse on the mandrel is annealed under heating/cooling conditions to achieve desired shape-memory alloy properties in the device. Various annealing methods are available including thermal heating and exposure to infrared heating in vacuum. An appropriate method of annealing is described in paragraph [0076]. Here, the specification outlines that sample B is produced by the same SHS process as sample A, but further includes a step of annealing at given process conditions. Comparing the structure of sample A having “splashes” in Figure 3 and described in paragraph [0063] with sample B of Figure 5, we note that the “undesirable titanium rich phases of sample A have disappeared in sample B after annealing, therefore annealing has caused the splashes to become smaller and it would be clear to the person of ordinary skill that these titanium enriched phases had become spheroid and therefore less likely to propagate cracks. Therefore, the Applicant submits that understanding the principles of annealing, one of ordinary skill in the art could arrive at steps that would affect the mechanical properties, the number and the size of the titanium and nickel enriched secondary phases present in the product with the guidance of the claims and the description submitted in the present application.

The applicant would like to advise the Examiner that in the counterpart European Case claims of very similar scope as those pending in the present application have been allowed in European Patent EP 1 663 330 B1.

The Applicant has included new claim 13, directed at a preferred embodiment of Ti-enriched secondary phases having oxygen comprising 13 to 14.6 atomic %. Support for this amendment is found at page 19, Table 11.

For the benefit of the Examiner, an updated Information Disclosure Statement has been filed concurrently with this submission, and includes the non-patent references discussed in this submission.

The Applicant respectfully submits that the claims on file would be understandable to the willing and person of ordinary skill in the art, who would be able to produce the product,

understand the claims and thus enable the invention with some degree of routine trial and error testing of the process. Reconsideration is respectfully requested.

**Conclusion**

The Applicant submits that the claims presently on file are in condition of allowance and favourable action is earnestly solicited.

Respectfully submitted,

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